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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,400

02/02/2007

Zoser B. Salama

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8658

46002 7590 08/25/2009

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EXAMINER

NAZARIO GONZALEZ, PORFIRIO

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

08/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,400	<b>Applicant(s)</b> SALAMA, ZOSER B.	
	<b>Examiner</b> PORFIRIO NAZARIO GONZALEZ	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05/26/2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,11-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2,6-9,11-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 2 and 11 have been presently amended.

Claim 17 have been cancelled.

Claims 18-21 are newly added.

Claims 1, 2, 6-9, 11-16 and 18-21 are currently pending.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6-9, 11-16 and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The inclusion of the formulas (II) and (III) in claim 2 is new matter. Said formulas are not described or shown in the instant specification at the time the application was filed. The only formula, other than formula (I), described in the instant specification is the formula at page 40, lines 1-13.

### ***Response to Arguments***

Applicant's arguments filed May 26, 2009 traversing the rejection of the claims under 35 USC §112, second paragraph have been fully considered but they are not persuasive. Applicant have amended claim 2 by including formulas (II) and (III), which according to Applicant they represent a cationic complex when  $X_1$ ,  $X_2$  are calcium or magnesium and an anionic complex, respectively, when  $X_1$ ,  $X_2$  are alkyl and/or aryl residues. It is applicant's view

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that the inclusion of said formulas overcomes the rejection of claims 2, 6-9, 15 and 16 under 35 USC §112, second paragraph as being indefinite. The Examiner respectfully disagrees. The inclusion of said formulas is new matter. See above rejection. Further, the problem is when  $X_1$  and/or  $X_2$  is calcium and/or magnesium. Formula (I) is completely clear when  $X_1$  and/or  $X_2$  is lithium, sodium, potassium ions, alkyl and/or aryl residues. However, when  $X_1$  and/or  $X_2$  is calcium and/or magnesium said formula is not longer clear. Note that at page 40, lines 1-13 which shows a  $Ca^{2+}$  linking of two platinum complexes and forming a neutral complex. This representation is completely different from Formula (I) of claim 2. Thus, the rejection is sustained.

Applicant's arguments filed May 26, 2009 traversing the rejection of the claims under 35 USC §112, first paragraph have been fully considered but they are not persuasive. Applicant continues to argue that "a person skilled in the art, e.g., a medical scientist or a physician, would know how to administer the medicament for prophylaxis, e.g., based on the medical history of the patient and his/her family."

Applicant argued "that the articles cited by the Office refer to a number of specific cases, which can, however, not be readily generalized." Applicant points to the Basler and Groettrup article as an article that is "focused on prostate cancer and does not mention oxoplatin and as such provides little insight with regard to any prophylactic use of oxoplatin." Further, Applicant points to MALARONE™, an antibiotic which have been used for prophylaxis and therapy.

The purpose of the Basler and Groettrup article, as well as the other articles, was to show that there is nothing in the prior art that discloses or teaches the use of platinum complexes as a preventive treatment. Applicant's claimed invention, oxoplatin, is also a platinum complex. However, Applicant has failed to provide any evidence and/or article that support his position concerning prophylaxis. As for Applicant's mention of MALARONE™, the

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Examiner would point out that the use of an antibiotic as a prophylactic agent does not extrapolate to the prevention of cancer tumors. These are two different diseases which have a different genesis and are expressed in the patient differently. Therefore, absent of any evidence or data that shows the claimed invention, a platinum complex, as a preventive treatment one skilled in the art would not be able, without undue experimentation to use the claimed invention. Thus, the rejection of claims 11-14 under 35 USC §112, first paragraph is sustained.

***Allowable Subject Matter***

Claim 1 is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PORFIRIO NAZARIO GONZALEZ whose telephone number is (571)272-0641. The examiner can normally be reached on M-F (9:30 A.M.-6:00 P.M.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PORFIRIO NAZARIO GONZALEZ/  
Primary Examiner, Art Unit 1621

PNG  
August 23, 2009